LUMENIS®

510(K) SUMMARY

MAR 2 4 2013

FiberLase Endure CO2 Fiber

510(k) Number K 130164

Applicant's Name: Lumenis Ltd.
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Trade Name: ***FiberLase Endure CO2 Fiber***

Device Type: ***CO2 Laser fiber***

Preparation Date: January 20, 2013

Classification: **Regulatory Name:** Laser surgical instrument for use in general and plastic surgery and in dermatology
Product Code: GEX
Regulation No: 21 CFR 878.4810
Class: II
Classification Panel: General & Plastic Surgery

Device Description:

The ***FiberLase Endure CO2 Fiber*** is a hollow, semi rigid, light-conducting delivery fiber, 2 meter length, designed to transmit laser energy from the CO2 laser system to the treatment site. The fiber also transmits a low power red diode or helium neon laser aiming beam to assist in targeting the tissue to be treated.

Intended Use Statement:

The ***FiberLase Endure CO2 Fiber*** is intended for use in surgical procedures requiring ablation, vaporization, excision, incision and coagulation of soft tissue. The ***FiberLase Endure CO2 Fiber*** is indicated for use in open surgical procedures such as ENT surgery and laparoscopy and endoscopic procedures.

Predicate Devices: Substantial equivalence to the following predicate device is claimed:

Device Name	510k No	Date of Clearance
FiberLase CO2 Laser WaveGuide	K100384	April 12 , 2010

Performance Standards

FiberLase Endure CO2 Fiber was tested and complies with the following standards:

- ANSI/AAMI/ISO 11135-1:2007 Sterilization of health care products — Ethylene oxide
- AAMI TIR30:2001 Product adoption and process equivalency for ethylene oxide sterilization
- ISO 14971-1:2007 Risk management for medical devices
- IEC 60601-2-22 ed3.0:2007 – Medical Electrical Equipment - Part 2-22: Particular Requirements for Basic Safety and Essential Performance of Surgical, Cosmetic, Therapeutic and Diagnostic Laser Equipment.
- IEC 60825-1:2007 – Safety of Laser Products - Part 1: Equipment Classification, Requirements and User's Guide
- ANSI/AAMI/ISO 17665-1:2006 Sterilization of health care products — Moist Heat.

A detailed description follows in **Section 14.**

Performance Testing

Performance testing demonstrated that the ***FiberLase Endure CO2 Fiber*** is as safe and effective as the cleared predicate device.

Comparison with the Predicate Devices

The ***FiberLase Endure CO2 Fiber*** is a modification to its predicate device, the FDA-cleared Lumenis Fiberlase CO2 laser WaveGuide (K100384).

The intended use of the ***FiberLase Endure CO2 Fiber*** is identical to the intended use of its predicate.

Both the ***FiberLase Endure CO2 Fiber*** and the Lumenis Fiberlase CO2 laser WaveGuide systems are fibers that transmit laser energy from the laser system to the treatment site. Both devices are comprised of a laser connector and a 2 meter long delivery fiber.

The structures, the materials and the dimensions of the ***FiberLase Endure CO2 Fiber*** are identical to the cleared Lumenis Fiberlase CO2 laser WaveGuide fiber.

The minor difference between the ***FiberLase Endure CO2 Fiber*** System and its predicate device is an addition of an Autoclave sterilization method for reprocessing the fiber instead of single use ETO. The minor differences do not raise any new questions of safety or efficacy. Moreover, performance testing demonstrated that the ***FiberLase Endure CO2 Fiber*** is as safe and effective as the predicate device. Thus, the ***FiberLase Endure CO2 Fiber*** is substantially equivalent to Lumenis FiberLase CO2 Laser WaveGuide (K100384).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Lumenis, Limited
% Qsite
Mr. Yoram Levy
General Manager
31 Haavoda Street
Binyamina, Israel 30500

March 24, 2012

Re: K130164

Trade/Device Name: FiberLase Endure CO2 Fiber
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: March 06, 2013
Received: March 11, 2013

Dear Mr. Levy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

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INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K130164

Device Name: *FiberLase Endure C02 Fiber*

Indications for Use:

The *FiberLase Endure C02 Fiber* is intended for use in surgical procedures requiring ablation, vaporization, excision, incision and coagulation of soft tissue. *FiberLase Endure C02 Fiber* is indicated for use in open surgical procedures such as ENT surgery and laparoscopy and endoscopic procedures.

Prescription Use: __X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use: ____ (21 CFR 801 Subpart C)

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Neil R Ogden
2013.03.22 16:12:33 -04'00'

(Division Sign-Off) for MXM
Division of Surgical Devices
510(k) Number _K130164_____